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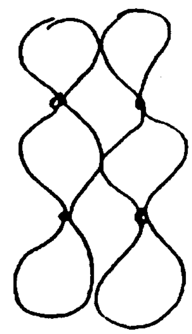
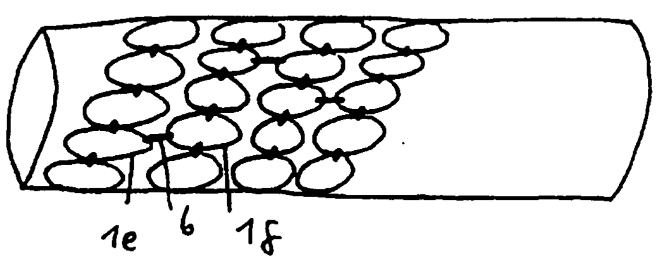
(54) Title: TUBULAR STENT

(57) Abstract

Stent in form of a tube like grid structure which consists of at least one sequence (i.e., one tubular segment) of closed loop or ring elements (1) which are connected with each other at at least one connecting point (4) per loop (loop contact point) wherein either the opposing ends of each sequence are circumferentially connected or one sequence is helically wrapped around the longitudinal axis of the stent. The closed loop elements are ellipses or have a half moon or bananalike shape.





Tubular Stent

Stents are used as support devices for tubular organs, in particular blood vessels.

Current stent devices include the Palmaz Schatz, Boneau, Fontaine, Fogerty, Hillsted, Williams, Gianturco Roubin, Gianturco self-expanding stent, to name some.

US 5 443 498 discloses a vascular stent that includes a continuous wire which is formed into a substantially tubular body having a plurality of oblong, open cells which are staggered around the circumference of the tube. When the body is formed in its unexpanded state, the long sides of each oblong cell are arranged substantially parallel to the longitudinal axis of the tubular body. Adjoining cells may then be bonded together at a point between adjacent parallel sides on a cell.

DE 44 32 938 A1 discloses a tubular or cylindrical shaped endo prosthesis which is applied to the (blood) vessel by using a balloon catheter. The endo prosthesis consists of a string formed by flexible segments which are substantially arranged in wave form and in a uniform manner along a helical line.

Conventional zig zag stents have to be rather short because the straight wire segments prevent the stent from easy adaption to curves in the cavities or openings in the patient's body. Furthermore the expansion forces of customary stents decrease with the length of the stent. An attempt to overcome these drawbacks is the combination of a plurality of short stents by connecting them at their ends. Although these modified stents have better characteristics for certain applications, there is nevertheless still a need for elongate (self-expanding) stents which combine the above mentioned characteristics with a better functioning.

Furthermore a control of the deformation of the stent after its self-expansion or balloon expansion is strongly desired. US 5 019 090 discloses the manufacturing of a helical stent which consists of wrapping a wire around a cylindrical core in a helical manner. In this case all segments of the stent have the same length which leads to the drawback that the stent deforms in a non desired manner after radial compression because the angle bisector of the angle between each pair of seg-

ments does not extend parallel to the centre axis of the stent. Therefore DE 93 21 136 U1 discloses a way of manufacturing a stent which overcomes this problem and which has the desired feature of a controllable deformation.

Finally it should be noted that all the above mentioned stents have in common that they are manufactured from a single continuous wire.

From the foregoing it can be seen that the ideal vascular prosthesis should include several features: easy manufacturing, high flexibility, low profile, little material as possible, radial strength, high expansion rate, firm seating on application instrument, little recoil after expansion and no shortening upon expansion, versatility for use in different indications and anatomies and usable as balloon and self-expanding stent, depending on use of high or low memory material.

It is thus an object of the present invention to provide a stent that combines all requirements in a unique manner. The use of single closed loop elements for the proposed stent lends extreme stability and radial strength and low risk of disintegration of the stent structure as occurs with stents formed out of zig zag wires. Use of closed loop elements permits variations in structure, strength, configuration and physical properties of the stent by simple design changes. Alignment of closed loops permits use of different materials in one circumferential series of loop elements, resulting in the possibility to modify the physical properties of stent segments within a stent, thus rendering stents more adaptive to target vessel (organ) properties.

The forming of a grid structure consisting of at least one closed loop made of conventional material is an essential part of the present invention. The loop -

either itself or in combination with further loops - is formed in a tube-like shape which is known from the state of art. A single loop element is thus formed in a manner that only round passages and curves occur which don´t have sharp edges and borders. If a plurality of such closed loop elements is used the loops are attached to each other by welding, soldering, gluing or a similar technique. This leads to the advantage that different materials can be combined in contrast to the state of art where only one material is used. For example, it is possible to use a material having springiness for some loops and a material which is plastically deformable for the other loops. Therefore one obtains a stent with sections that have springiness and sections that are plastically deformable the stent thus being useful for a variety of applications.

The different embodiments of the stent according to the present invention are shown in the accompanying figures.

Fig. 1 A shows a sideview of a tubular segment of the unexpanded stent consisting of three closed loops in an circumferential arrangement.

Fig. 1 B shows a perspective view of an expanded stent consisting of an annular successive sequence of loop elements which are interconnected at one point.

Fig. 1 C shows the tubular segment of Fig. 1 A in the expanded state.

Fig. 2 shows two adjacent tubular segments which are interconnected by a backbone.

Fig. 3 A shows a loop element consisting of two parallel wires with a suitable connection of their ends.

Fig. 3 B shows a loop element made of a U-shaped wire with only one connection between the adjacent ends of the wire.

Fig. 3 C shows a sequence of two loop elements each of which has a connecting point in its midportion.

Fig. 4 A shows a tubular segment consisting of loop elements which have different length in the longitudinal direction.

Fig. 4 B shows a stent which consists of the tubular segments of Fig. 4 A.

Fig. 5 A shows a tubular segment with the loops being symmetrical about their major and minor axes as in an ellipse.

Fig. 5 B shows a tubular segment with the loops having a banana like shape thus being asymmetrical about a longitudinal midline along their major axes when unexpanded.

Fig. 5 C shows the tubular segment from Fig. 5 B being symmetrical about a longitudinal midline along their major axes when expanded.

Fig. 5 D shows a tubular segment with the loops having a wave like shape.

Fig. 5 E shows a tubular segment with the loops consisting of small circles.

Fig. 6 A shows two adjacent tubular segments which are interconnected in such a way that the connecting points are arranged at the ends of the banana like shaped loops along a longitudinal line parallel to the longitudinal axis of the stent.

Fig. 6 B shows two adjacent tubular segments which are interconnected by a backbone which is arranged along a sinusoidal line parallel to the longitudinal axis of the stent.

Fig. 7 A shows a stent which has been manufactured by arranging the loop elements helically around a cylinder.

Fig. 7 B shows the stent from Fig. 7 A wherein only the first and the last loop elements are connected to an adjacent loop element on an adjacent helical turn.

Fig. 7 C shows the loop elements being interconnected at their midportions to form a chain.

Fig. 7 D shows the loop elements being interconnected outside of their midportions to form a chain.

Fig. 7 E shows the stent from Fig. 7 B but with more loops being connected to an adjacent loop element on an adjacent helical turn.

Fig. 8 A shows a closed loop element which is segmented by connecting the opposing loop sides at two points.

Fig. 8 B shows a longitudinal arrangement of loop elements from Fig. 8 A.

Fig. 8 C shows a horizontically segmented loop element.

Fig. 8 D shows a circumferential sequence of loop elements from Fig. 8 C.

Fig. 9 A shows the stent from Fig. 7 A being kept in its unexpanded state by a mechanism which exerts longitudinal or circumferential traction.

Fig. 9 B shows the stent from Fig. 9 A after expansion.

Fig. 10 A shows three longitudinally arranged tubular segments wherein at least one loop element has a different functional material property in comparison to the others.

Fig. 10 B shows three longitudinally arranged tubular segments wherein balloonexpandable tubular segments alternate along the longitudinal axis of the stent with self-expandable tubular segments.

Fig. 11 shows two longitudinal arranged tubular segments which are interconnected in the longitudinal axis by a closed loop element.

Manufacturing, material, micro structure

Fig. 1 A/C shows a tubular segment of the stent according to the invention which consists of single closed loops in the unexpanded/expanded state. Each loop is

connected with its adjacent loops. Fig. 1 B shows the stent which consists of a longitudinal sequence (with respect to the longitudinal axis of the stent) of these tubular segments. Possible variations of this stent structure are described below.

The stent consists of single loops or rings or sequences of these loops or rings which have an oval or circular crossection (Fig. 1 A / 5 A) and which are arranged in circumferential or longitudinal direction having at least one interconnection. The single loops may be formed with round wire by connecting its ends through welding, soldering, gluing etc. (Fig. 3 A/B) or they may be cut from tubes or flat material.

The originally formed loop element can correspond to a „compressed", i.e. unexpanded, form (small diameter of the stent) , or to a completely expanded form (large diameter of the stent). Depending on the material and its strength it may be more suitable for the manufacturing process and the physical characteristics of the stent to fold a basic form (which corresponds to the expanded or partly expanded diameter of the stent) on a balloon of a balloon catheter or to compress it or to fold a basic form (which corresponds to the compressed diameter) on the balloon. In the last case the stent or its loop is deformed far beyond its basic form, in the first case it is only partly deformed beyond its basic form or even not deformed at all. The diameter of the basic stent form or its loop form is substantial for the deforming characteristics and the collaps resistance of the expanded stent.

The number of loops of a sequence in circumferential direction (which is the expanding direction) depends on the necessary diameter of the expanded stent (for the maximal expansion of the stent for a predetermined vessel diameter). Furthermore it depends on the acceptable contraction of the whole structure. In

addition to the strength of the material the number of loops in circumferential direction determines the collaps resistance of the stent. The collapse resistance also partly depends on the opening angle of the sides of the single loops which open on expansion. The recoil of the expanded loop is smaller for larger opening angles than for smaller opening angles.

The substantial variables for the modification of the stent´s characteristics are the number of loops, the material used, the combination of loops made of different material, the strength of the material, and the opening angles of the sides of the loops during the (implanted and partly expanded) functional state of the stent.

The basic form of a sequence of loops may also be formed by parallel extending pairs of wire in that the ends (or the pair of ends for a U-shaped wire) are connected (Fig. 3 A/B) and in that the resulting wire loop is connected to the next wire loop at a point preferably in the midportion of the U-shaped ends (Fig. 3 C).

Different configurations of the stent (macro structure)

a) A sequence, i.e. a „chain" of loop elements can form a very short stent structure by connecting their ends in circumferential direction. An arbitrary length of the stent can be obtained by lining up such tubular segments in longitudinal direction with or without connecting them at discrete points Fig. 2). A loop sequence in longitudinal direction can also be used as the basic element in that sequences with the same length are lined up in circumferential direction and are connected with the adjacent loop elements in circumferential direction.

b) Instead of lining up tubular segments, i.e. sequences of single loops, a helical wrapping of a chain of single loops (Fig. 7 A) can lead to a similar (very long, if desired) stent structure. The ends of the loop chains don´t have to be connected but they may be connected with the adjacent loop element in longitudinal direction (7 B/E). This (helical) configuration is very flexible in longitudinal direction and leads to a good seating on the balloon or a similar dilatation elements. Both a) and b) have portions of stent structures that extend more parallel and portions that extend more vertical to the longitudinal axis of the vessel.

c) Furthermore a single loop which is sufficiently large and which has a sufficient side length in circumferential direction can be wrapped circularly (with interconnected U-shaped ends) or helically (without interconnected ends) around the balloon or the dilatation element. In the first case, i.e. with a circular wrapping and connected U-shaped ends, wave like configurated loop sides are requested to keep the expansion ability of the structure during (balloon) dilatation.

In case of a helical wrapping of the loops around the dilatation element the loop sides can extend in a wave like manner. A particular embodiment of the helical wrapping is a change of the winding direction at least once after at least 360° in the same direction.

The helical configurations have a particularly good seating on the balloon (dilatation element) and a large flexibilty. Preferably the stent structure does not extend parallel to the axis of the vessel but helically or circumferentially.

If the loop sequences are not connected to the adjacent sequences in a longitudinal direction already during manufacturing the loop chains (c.f. a)) can be con-

nected in longitudinal direction by conventional soldering, gluing, welding, laser, electro and other methods. If a shortening of the total length of the stent shall be minimized during stent expansion a particular connection of adjacent loop sequences in longitudinal direction is desirable. To this end it is not the adjacent free loop sides which are connected but the connection is made at at least one contact point of the single loop elements with a separate connector. Thus, a fixed distance spacing is obtained between the loop sequences which are connected in longitudinal direction during expansion of the stent structure. This spacing connection can be formed always at the same circumferential position (e.g., always at 6 o'clock) or in form of a continuous connection (e.g., wire) corresponding to a back bone which leads to a high flexibility or in alternating positions (e.g., 6 o'clock, 12 o'clock, 6 o'clock and other changes of position) or leaving out certain sequences (less effective for keeping the spacing). The spacing connection or the above mentioned separate connector is made of very flexible material (e.g., thin wire). Thus the length flexibility of the stent is better than the one which is obtained by using connections of the loops with soldering, welding etc.

Particular configurations of the single loop elements can be used for additional ends:

Instead of an even extension of the material which forms the loop (e.g., wire) this material can also extend in a wave like form and a single loop of a sequence of loops may have a flower or star like structure (Fig. 5 D). This structure allows isolated expansion of a single loop, e.g., for the passage of a catheter through a loop in a side wing for the dilatation of a side wing stenosis.

Furthermore a single loop or all single loops in connection with a sequence of loops in circumferential direction (expansion direction) can have a (non-expanded) wave like basic form (Fig. 5D), so that the shortening of the stent in longitudinal direction is minimized during expansion of the sequence of loops. This wave like structure of a sequence of loops does not have to be (but may be) obtained by a special folding of another basic structure, but may be partly or solely manufactured as such a basic structure.

Such an expanded single loop or a single ring may also consist of a chain of loops or rings (Fig. 5 E).

Combination of different materials for the stent

The loop structure according to the invention is useful - as mentioned - for purely spring elastic stent materials and also for stent materials which are plastically deformable beyond their limit of elasticity.

Sequencing of segmented (Fig. 8 A-D) or unsegmented (Fig. 1 A-C) single loops in circumferential direction for the manufacturing of a stent leads to the possibility to use different materials in a stent or in a loop or ring sequence. Thus a circular sequence of loops can be formed which are made of plastically deformable and spring elastic material (Fig. 10 A/B). At least one loop of a sequence in circumferential direction may consist of a different material and/or have different characteristics compared to the other loops of the sequence.

The sequence of loops which follows in longitudinal direction may contain the different loop at the same (e.g., 6 o'clock to 6 o'clock) or at a different (e.g., 6 o'clock to 8 o'clock) position. Thus modifications of the characteristics of the stent with mainly spring elastic characteristics may be obtained by using plastically deformable loops and visa versa. These combinations lead to new applications and versatility.

A mixture of materials may also be used in large single loops (see c)) or in a helical configuration of sequences of loops (see b)).

Methods of application of the stent to a dilatation element (e.g., balloon), application system

Balloon expandable stents

The stents are pre-manufactured with a certain first inner diameter (D1) and are applied to the dilatation element either during the manufacturing process or by the medical staff. Then they are compressed to a smaller diameter (D0) either manually or by using a compression tool depending on the stent or the diameter of the balloon catheter. During expansion of the dilatation element the stent is expanded to a large diameter (D2) and will be left at the desired position after taking away the application system. A single short closed loop stent, a sequence of single unconnected closed loop stents and closed loop stents which are connected in longitudinal direction are applied in the same manner. Helical stents are preferably delivered in finished helical form and with the above mentioned inner diameter (D1) or they are already applied to the balloon catheter or the dilatation element with the inner diameter (D0). Helical stents may also be provided in an

unhelical form and may be wrapped on the dilatation element by the medical staff.

All stents may already be applied to the dilatation element and may have a protection cover which can be drawn away during the surgery to avoid the loss of the stent during the application.

Self-expanding stents have to be kept on the dilatation element or on the application system (without a dilatation possibility) in a compressed and fixed state (inner diameter D0), e.g., by gluing, tying (with a rated breaking point of the retaining thread), or by using other retaining mechanisms which are connected to release mechanisms. Self-expanding stents are preferably pre-applied.

A stent material made of a temperature memory alloy may ease the application of self-expanding stents to the application system or dilatation element.

Helical stents can be kept with a small diameter and fixed on the application system or dilatation element by applying a mechanical traction which acts in longitudinal direction. Release, e.g., cutting the retaining thread or breaking the retaining system (thread, gluing etc.), during the balloon expansion (in case the application system is a dilatation element or a balloon) lets the helical stent jump to

its functional diameter (D1 and/or D2). Thus the total length of the stent may decrease. This shortening may be balanced in that the single rings or loops which make up the helical structure are also compressed and take their basic form, i.e., loop or ring form, after release of the retaining mechanism through self-expansion. This configuration is far superior to pure coil configurations.

<u>Mixture of spring elastic material with material which is plastically deformable beyond its limit of elasticity in one stent</u>

Using of at least one spring elastic ring (or loop) in a preferably circumferential (but in longitudinal direction) sequence of plastically deformable (and conventional balloon expandable) rings (loops) can improve the characteristics of the stent (e.g., smooth and continuing self-expansion of a balloon expandable stent after application). Or visa versa: a self-expandable stent can be balloon expanded in its end section (D2) by using plastically ring elements in a preferably spring elastic stent.

The purely plastically deformable ring or loop elements can be arranged in such a way that they keep the single spring elastic elements or the sequences of spring elastic elements in a compressed form.

Advantages of the loop structure according to the invention

- Versatile usage of a basic structure with easy manufacturing.
- High flexibility of the stent and thus for complex surgeries, difficult anatomy of the vessel, e.g., vessel curves and for very long stenosis.
- Convenient relation between free surface and surface which is covered with material which relation is easy variable by changing the number of the loops in a sequence.
- Ring or loop design without sharp edges, protruding wires, even if the stent is not manufactured of round wire material as its basic form.
- Easy modification in the manufacturing leads to a narrow or a wide network.
- New design which can be used for balloon expandable and/or self-expandable stents.
- Safe seating on the balloon because of round or oval loop material in it's cross section with partly circular or helical configuration.
- Design leads to best collapse resistance and to a tendency towards ring form of the elements in their functional state.
- New possibility of mixing materials in one stent.
- No desintegration (like in zig zag wires).

Avoided drawbacks of conventional stents

- Faulty collapse resistance for helical structures or zig zag patterns made of continuous wire.
- Protruding wires in continuous wire wrappings, especially curves.
- Sharp edges if manufactured of tube sections.
- Stiffness of most stents which are cut of tube sections.
- Stiffness because of too long longitudinal wires in zig zag wires.
- Tapping of the free stent ends and therefore clutching of the stent and loss of the stent in case of wire and block stents.
- Too thick profile which is necessary for collapse resistance.
- Desintegration.

Claims

1. A tubular (vascular) stent comprising a series of at least 3 circumferentially arranged closed loop elements (1) cut from wire or from flat or tubular material, each of said loop elements having only one major longitudinal axis (2) and one minor circumferential axis (3), wherein said loops are aligned with their respective major axis in a parallel manner and their minor axis perpendicular to the longitudinal axis of the stent, each of said closed loop elements being connected to each circumferentially adjacent closed loop element at a discrete point (4) in the midportion of each major axis so that each closed loop element is having two opposing connecting points, and arranged circumferentially (circularly) around a (thought) cylinder (5) such that the series of closed loop elements form a tubular (stent) segment having a proximal and a distal end and a tubular diameter D1.

2. The stent of claim 1 wherein upon expansion the minor axis (3) of each loop increases in length and the tubular segment assumes diameter D2, wherein D2 is greater than D1.

3. The stent of claim 1 or 2 having at least 2 tubular segments (5a, b) arranged along the longitudinal axis, said tubular segments being connected to each other by at least one longitudinal element (backbone) (6), said longitudinal element being attached at the circumferential interconnecting points (4a, b) of the single closed loops which form the tubular segment

4. Stent of claim 3 wherein the length of the major axis (2a) of at least one of the closed loop elements (1a) forming a tubular segment is unequal to the length

of the major axis (2b) of at least one circumferentially adjacent closed loop element (1b) and if such difference in length of the major axes of closed loop segments is used as an end segment in a tubular segment representing the end-segment, the plane of the end (7) of the stent is non-perpendicular to the longitudinal axis (8) of the stent.

5. Stent of claim 4, wherein the length of the minor axis (3) of at least one of the circumferentially arranged closed loop segments (1) forming a tubular segment is unequal to the length of the minor axis of at least one circumferentially adjacent closed loop segment.

6. The stent of claim 3 wherein the only longitudinal element / backbone (6) connecting the tubular segments is a single straight or sinusoidal element, the major longitudinal axis of which is parallel to the longitudinal axis (geneatrix) (8) of the stent.

7. The stent of claim 1 wherein each of said closed loop elements (1) is symmetrical about its major and minor axis (2 and 3) as in an ellipse.

8. Stent of claim 1 wherein each of said loop elements (9) is asymmetrical about a longitudinal midline (10) along its major axis and forming loop elements of half moon or banana like shapes, so that during expansion of the closed loop element (9) the length of the minor (circumferential) axis (3) increases without significant decrease of the length of the major (longitudinal) axis (2) until symmetry or near symmetry about a longitudinal midline along its major axis is reached.

9. Stent of claim 8 having at least 2 tubular segments (1a, b) arranged longitudinally, wherein adjacent tubular segments are connected by connecting at least two longitudinally adjacent ends of the major axis of the loop elements, wherein the connecting points (12a, b) are arranged along a longitudinal line parallel to the longitudinal axis (8) of the stent (geneatrix) or a helical line winding around the cylindrical shape of the stent.

10. Stent of claim 8, wherein the tubular segments (11a, b) formed by assymetrical closed loop elements (9a, b) are interconnected longitudinally by a sinusoidal longitudinal element (13) attached to the circumferential interconnecting points (12a, b) of the closed loop elements, said longitudinal element (13) running parallel to the waveform created by the thought connection of the ends of the major axis of the asymetrical loop elements.

11. The stent of claim 1 or 2 wherein the stent is expandable by a ballon or other means.

12. The stent of claim 1 or 2 wherein the stent is selfexpandable.

13. Stent made of a series of closed loop elements (1) cut from wire or from tubular or flat material, each of said closed loop elements (1) having a major longitudinal and a minor circumferential axis (2 and 3) and wherein said loop elements (1) are connected to each other at a discrete point (4) to form a chain of closed loop elements and wherein the series of loop elements (chain of loop elements) is arranged helically around a cylinder (5′) such that the series of loop elements forms a tubular segment with a proximal and distal end and having a diameter D1.

14. Stent of claim 13, wherein upon expansion the length of the minor axis (3) of each closed loop element increases and the tubular segment assumes diameter D2, wherein diameter D2 is greater than D1.

15. Stent of claim 13, wherein only the first loop (1c) and the last loop (1d) of the helically arranged chain of loop elements are connected to an adjacent loop element on an adjacent helical turn.

16. Stent of claim 15, wherein at least 2 loops (1e and 1f) of adjacent helical turns are connected to the neighbouring loop along the longitudinal axis of the stent by a connecting element (6).

17. Stent of claim 16 wherein such connection is between the connecting points of the helically arranged loop elements.

18. Stent of claim 13 wherein the loop elements are elliptic.

19. Stent of claim 13 wherein the loop elements have banana form, i.e. they are asymmetrical about their major axis.

20. Stent of claim 13 wherein the closed loop elements (1) are interconnected at a discrete point (4′) at their midportion to form a chain.

21. Stent of claim 13 wherein the closed loop elements (1) in their unexpanded state are interconnected to form a chain at discrete points (4″) outside of their midportions.

22. Stent of claim 13 wherein the stent is expandable by a balloon or other means.

23. Stent of claim 13 wherein the stent is selfexpandable.

24. Stent of claim 23, wherein the stent is held in its non-expanded state by a mechanism (14) which exerts longitudinal or circumferential traction and said helically structured stent is assuming its expanded state upon release of such restraining tensile mechanism.

25. Stent of claim 1 or 2, wherein at least three tubular segments (1) formed by a series of circumferentially arranged closed loop elements are aligned longitudinally, said tubular segments being connected by a connection (6) of the ends of the major axis (2) of each said closed loop elements to the end of the major axis of the longitudinally adjacent loop element, wherein at least one closed loop element (1´) is having a different functional material property in comparison to at least one of the loop elements to which it is connected.

26. Stent of claim 25, wherein primarily balloonexpandable tubular segments (1´´) alternate along the longitudinal axis (8) with primarily selfexpandable tubular segments (1´´´), said selfexpandable tubular segments being held in their nonexpanded state by the adjacent balloonexpandable tubular segments in their nonexpanded state.

27. Stent of claim 1 or 2, having at least two longitudinally arranged tubular segments (5a, b), said tubular segments being connected in the longitudinal axis

(8) by at least one closed loop element (15), said connecting closed loop element being attached to two ends of the major axis of two adjacent closed loop elements of a tubular segment.

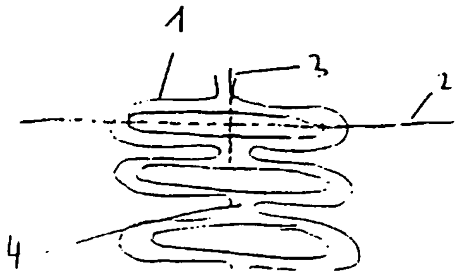


Fig. 1A

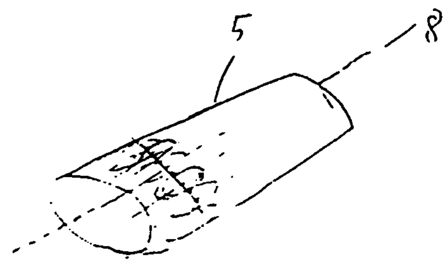


Fig. 1B

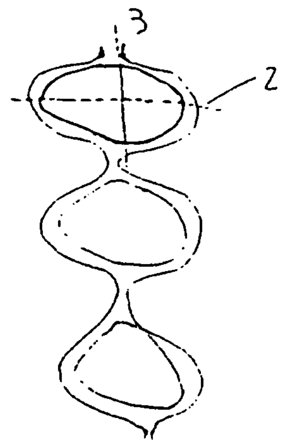


Fig. 1C

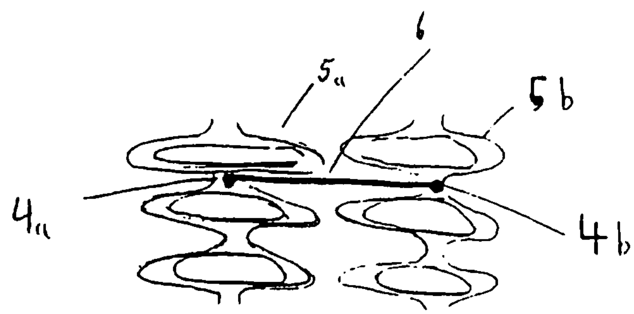


Fig. 2

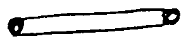


Fig. 3A

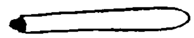


Fig. 3B

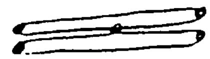


Fig. 3C

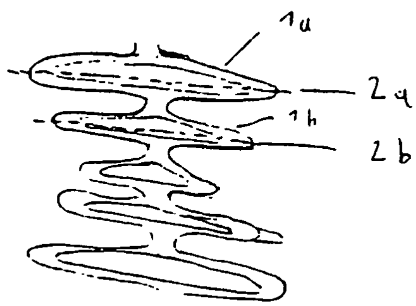


Fig 4A

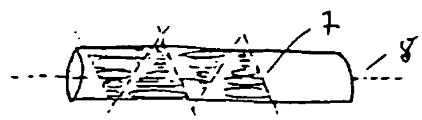


Fig 4B

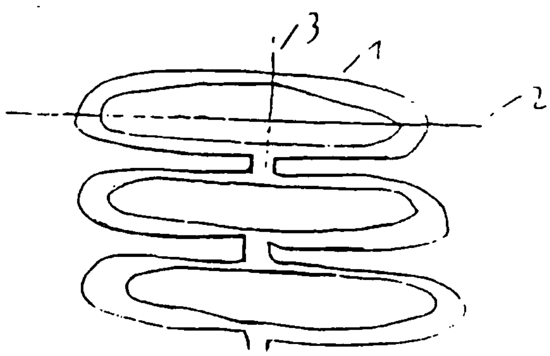


Fig 5A

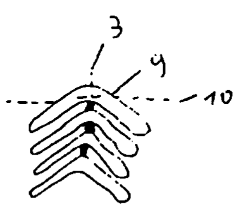


Fig. 5B

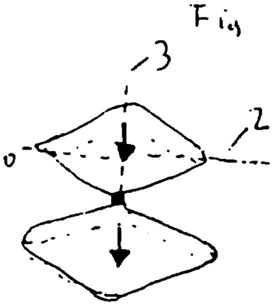


Fig. 5C

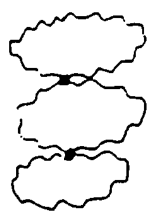


Fig. 5D

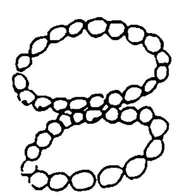


Fig. 5E

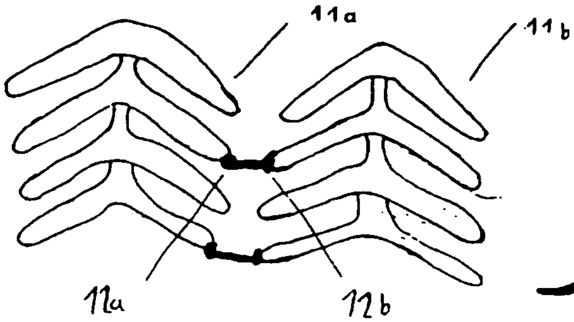


Fig 6A

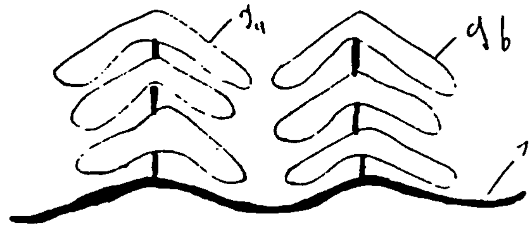


Fig. 6B

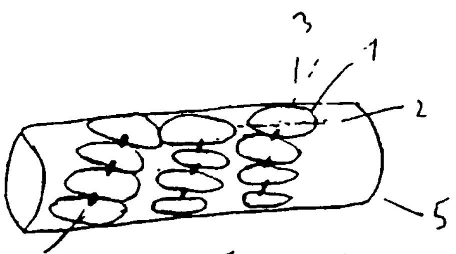


Fig. 7A

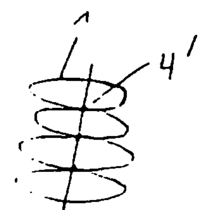


Fig. 7C

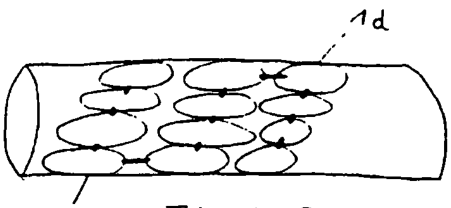


Fig. 7B

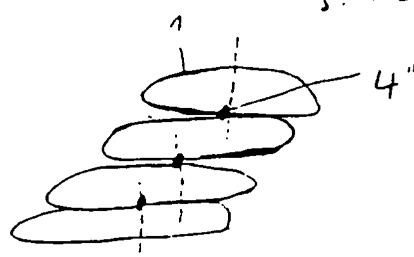


Fig. 7D

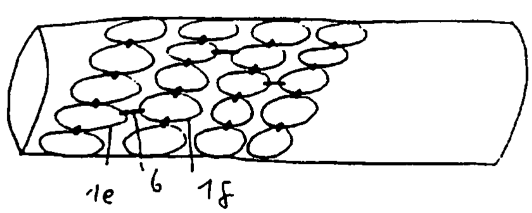


Fig. 7E

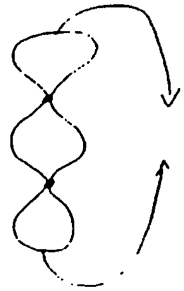


Fig. 8A

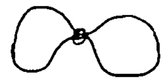


Fig. 8C

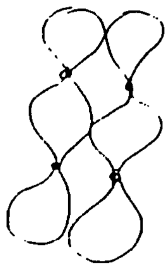


Fig 8B

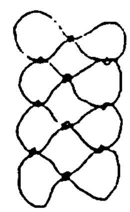


Fig 8D

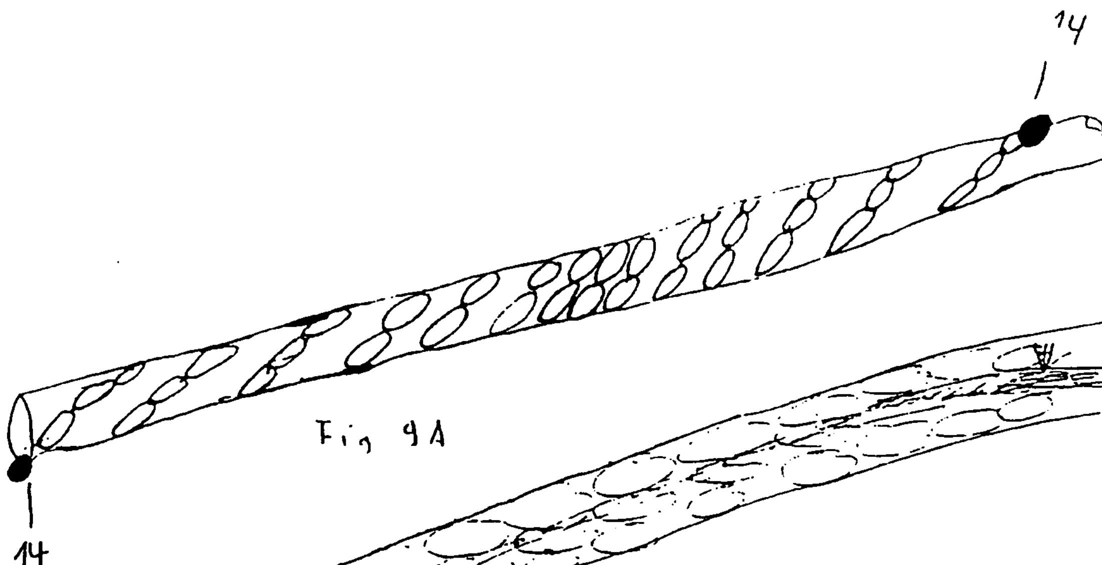


Fig 9A

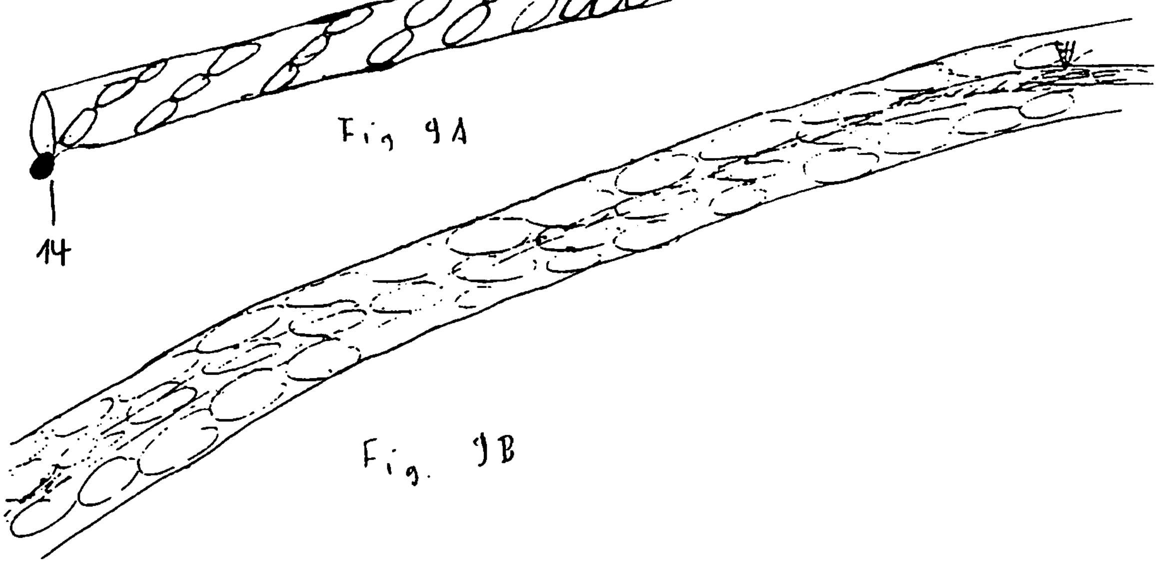


Fig. 9B

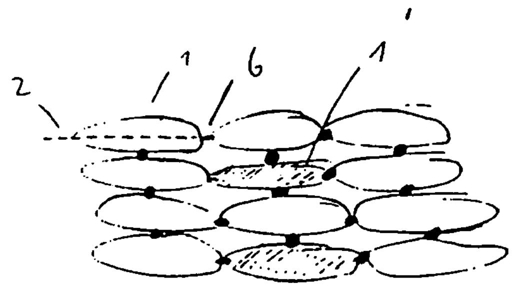


Fig 10 A

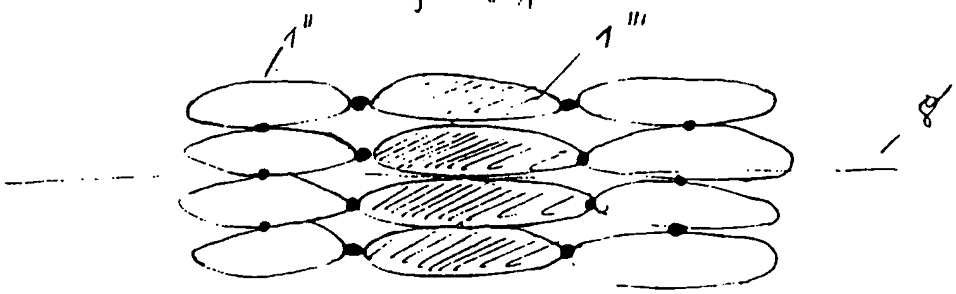


Fig. 10 B

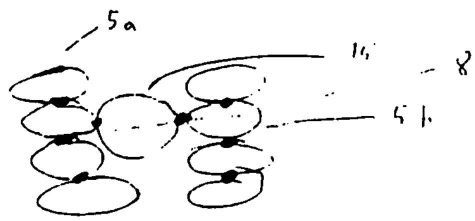


Fig. 11

INTERNATIONAL SEARCH REPORT

Int: ional Application No
PCT/EP 97/04585

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
E	EP 0 795 304 A (TERUMO) 17 September 1997 see abstract; figures	1-3,6,7
P,X	EP 0 790 041 A (ALT) 20 August 1997 see abstract; figure 9	1,4,7
P,X	WO 96 33672 A (IMPRA) 31 October 1996 see abstract; figures	1,2
X	EP 0 565 251 A (COOK) 13 October 1993 cited in the application	13,14,22
A	see abstract; figures	1
A	WO 95 31945 A (SCIMED LIFE SYSTEMS) 30 November 1995 see figure 10D	8,19

[ ] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 December 1997	20/01/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Hagberg, A

INTERNATIONAL SEARCH REPORT

Int'   tional Application No
PCT/EP 97/04585

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